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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,613	01/03/2002	Y Tom Tang	PF-0711 USN	8308

7590 09/05/2003

Legal Department
Incyte Corporation
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER
SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,613	TANG ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11,13-19,22 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *1,2,10,13-19,22 and 25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3-7,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-7,9-11,13-19,22 and 25-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Office Action

1. Applicant's election with traverse of Group III, (pending claims 3-7 & 11), drawn to a polynucleotide (SEQ ID NO : 3) encoding SEQ ID NO : 1, in Paper No. 6 is acknowledged. Applicant traverses the lack of unity requirement (beginning at page 9 of Paper No. 10) by stating that the unity of invention standard must be applied in national stage applications. Applicant cites sections of MPEP § 1800 in support of their statements. In response to applicant's statements, it is noted that the unity of invention standard *was* applied to original claims 1-28 in evaluating the claims for unity of invention and restricting the claims according to 35 U.S.C. 121 and 372. MPEP § 1893.03(d) states, "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted". Also, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. As stated in the Office action of Paper No. 4, the inventions of original claims 1-28 do not relate to a single general inventive concept because the shared technical features of the claimed polypeptide and polynucleotide lack novelty or inventive step and therefore, do not make these technical features a contribution over the prior art. See the Office action of Paper No. 6 for reasons why the inventions of original claims 1-28 lack unity of invention. In accordance with MPEP § 1893.03(d), the examiner properly applied the unity of invention standard to original claims 1-28 in the instant application.

Beginning at the top of page 10 of Paper No. 6, applicant cites Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, which states:

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicant argues the examiner should withdraw the lack of unity requirement with respect to claims of Group I, drawn to the special technical feature of a polypeptide, and co-examine the claims of Group I with the elected claims of Group III. Applicant argues unity of invention exists for claims drawn to the polypeptide of SEQ ID NO : 1 and claims drawn to the elected corresponding encoding polynucleotide of SEQ ID NO : 3 based on the rules concerning unity of invention under the PCT and Example 17 as stated above. Applicant's argument is not found persuasive. According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Furthermore, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions of Groups I and III do not have unity of invention because they do not share the same technical feature of Groups I and III irrespective of there contribution over the prior art, as explained in the prior Office Action.

Beginning at the middle of page 11 of Paper No. 6, applicant cites sections of MPEP § 1800 and argues that claim 10, drawn to antibodies, should be examined together with claim 1,

drawn to polypeptides from which claim 10 depends. Moreover, claims 2-3, 10, 16, 17, all of which depend from claim 1, are all directed to composition of matter, i.e., to products. Further, as discussed above, there is unity of invention among claims 1, 3 & 11. Applicants further argue that unity of invention exists among all of Applicants' claims, which serve to technically interrelate all of Applicants' claims.

Applicant's argument is not found persuasive. As stated above, there is no unity of invention between the polypeptide of Group I and the polynucleotide of Group III. Therefore, claims dependent from claims 1, drawn to an antibody that binds the polypeptide of Group I, do not have unity of invention with the claims of Groups I and III because the polynucleotide of Group III shares no corresponding technical feature with the polypeptide of Group I. Furthermore, applicant's argument that claims 1-3, 10, 16, 17, all of which depend from claim 1 have unity of invention with the claim from which they depend, is misplaced. As is further explained in MPEP 1850, if an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity may be raised. As has been previously explained, the polynucleotide of Group III and the polypeptide of Group I do not constitute a special technical feature and thus there is no inventive link between the polynucleotide of Group III, the polypeptide of Group I and the antibody of claim 10. It should be noted that claims of Group III which depend from the claims of Group I are not dependent claims that have unity of invention within the meaning of MPEP 1850(A) as the polynucleotide claims of Group III which depend from the polypeptide claims of Group I do not have all the

features of the polypeptide, i.e., polypeptides and polynucleotides are *chemically distinct* compounds.

Beginning at the top of page 12 of Paper No. 6, after the MPEP recitation, Applicant argues unity of invention exists among all of the pending claims. Applicant argues the claimed polypeptides and encoding polynucleotides are corresponding technical features, which are common to all pending claims, which serve to technically interrelate all pending claims, and which define the contribution over the prior art. Applicant argues the pending claims are linked to form a single general inventive concept, and applicant is therefore entitled to prosecute all pending claims in a single application. Applicant's argument is not found persuasive. As stated above, the polynucleotide of Group III does not share a corresponding special technical feature with the polypeptide of Group I. Furthermore, 37 CFR § 1.475(d) does not provide for the inclusion of multiple methods of use within the main invention. As claim 9 is the first claimed method of using the polynucleotide of Group III, this claim will be included and co-examined with the claims of Group I. However, the *additional* methods of use of the polynucleotide of Group VI and methods of using the polypeptide of Group II do not have unity of invention in accordance with PCT Rule 13.2 and 37 CFR § 1.475(d). Therefore, the polynucleotide of Group III, the polypeptide of Group I, the antibody of claim 10, *additional* methods of using the polynucleotide of Group III, and methods of using the polypeptide do not have unity of invention. Claim 9, drawn to a method of producing a polypeptide using a host cell comprising a recombinant polynucleotide, is now the first claimed method of using the polynucleotide of Group III and will be co-examined in accordance with 37 CFR § 1.475(d).

Beginning at the top of page 13 of Paper No. 6, applicant argues the sequences of the claimed polypeptides and corresponding polynucleotides are common to all pending claims. Applicant argues the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of applicant's claims. Applicant argues the composition of matter claims are drawn either to the claimed polypeptides or polynucleotides themselves, to compositions of matter that comprise the polypeptides or polynucleotides as one element, or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter. Applicant argues that in the method-claims.., the claimed polypeptides or polynucleotides serve as either the product of the claimed method and/or as a reagent for performing the method. Applicant's argument is not found persuasive. The examiner acknowledges that the polynucleotide of SEQ ID NO : 3 encodes the polypeptide of SEQ ID NO : 1. However, the polynucleotide of elected Group III is *not* limited to the polynucleotide of SEQ ID NO : 1. As stated above, the polynucleotide of Group III (including host cells & method of making polypeptide), the polypeptide of Group II (including compositions and methods of use thereof), the antibody of claim 10 and the *additional* methods of use of the polynucleotide do not share a corresponding technical feature and/or are *additional* methods of use of an invention that already includes a method of use do not have unity of invention in accordance with PCT Rule 13.2 and 37 CFR § 1.475(d).

Beginning at the bottom of page 13 of Paper No. 6, applicant argues there is minimal additional burden to examine claims 13-15 (Group XIII), 27 (Group XIX) & 28 (Group XXI). Applicant argues the search for the subject matter of these claims should substantially overlap with the examination of the polynucleotides of Group III. This is not found persuasive, because

searching of DNA [class 536, subclass 23.3], will not recover polypeptide art, classified in class 435, subclass 69.1. Furthermore, as stated above, *additional* methods of use and 37 CFR § 1.475(d) does not provide for the inclusion of multiple methods of use within the main invention.

This additional searching as explained above would therefore involve undue burden to the Examiner. The requirement is still deemed proper and is therefore made FINAL.

2. **Claims 3-7, 9 and 11** [SEQ ID NO : 3 encoding SEQ ID NO : 1]are under consideration in this Office Action.

3. Claims 8, 12, 20-21 & 23-24 have been canceled by the above cited amendment. New claims 29-30 have been added.

4. Claims 1-2, 10, 13-19, 22, 25-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

5. ***Objection***

The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, page ***, line ***) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

See page 2, lines 6-7 of the instant specification, for example. Applicant's cooperation is requested in correcting any errors, including hyper-links which may be present in the specification, of which applicant may become aware of in reviewing the specification.

6. ***Written Description***

Claims 3-7, 9 & 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NO: 3 having the limitations of encoding a protein having the sequence of SEQ ID NO: 1, which is 90% identical to the sequences with no defined function or a DNA sequence which 70% similar to SEQ ID NO : 3.

The specification does not contain any disclosure of the function of all DNA sequences that are 70% or 90% identical to various SEQ ID NOS: and the claims do not recite these sequences to encode a protein by its discovered function. Further, the specification does not describe specific assays to measure the various polypeptide sequences having the said activity or which is so evident, as none is described. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only 2 species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

7. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-7, 9 & 11 are rejected under the judicially created doctrine of double patenting over claims 1-13 of U. S. Patent No. 6,524,819 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application [common assignee, different inventors] are claiming common subject matter, as follows: Applicants' Polynucleotide (SEQ ID NO : 3) encoding the polypeptide of SEQ ID NO : 1 is disclosed in the cited patent and is 100% identical, is comprised by the polynucleotide sequence of SEQ ID NO : 1 (or encoding the

polypeptide sequence of SEQ ID NO : 2) disclosed in cited USP '819. The reference anticipates the claims.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tekchand Saidha
Primary Examiner, Art Unit 1652
September 4, 2003